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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/025,282

12/19/2001

Mark W. Bleyer

3433-333

5918

7590

07/26/2006

Woodard, Emhardt, Naughton, Moriarty and McNett

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/025,282

Applicant(s)

BLEYER ET AL.

Examiner

Maria Leavitt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-60 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-60 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Claims 36-60 and 62 are pending. Claims 38, 39, 45, 46, 53, 54, and 55, have been amended, claim 61 has been cancelled and claim 62 has been added by amendment dated 06-05-2006.

Response to arguments

3. Remaining rejections in response to Applicant arguments or amendments

35 U.S.C. 112, first paragraph, written description

Claims 54 and dependent claims 55-60 remain rejected and new claim 62 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

On page 1 of Remarks, Applicant argues that claim 54 has been amended to specify that the multi-layer bioabsorbable collagenous biomaterial “comprises a material isolated from a warm-blooded vertebrate tissue source”. Though the source of the bioabsorbable biomaterial is disclosed in the as-filed specification, Applicant has not properly addressed the grounds of rejection as stated in the previous office action mailed on 11-28-2005. Applicant does not provide sufficient guidance to demonstrate that he is in possession of any variety of suitable bonding techniques and materials as embraced by the invention and set forth and claimed. Though, Applicant argues that a number of bonding techniques are disclosed in the as-filed

Art Unit: 1633

specification, the scope of the invention as embraced by claim 54 and its remaining dependent claims 55-60 and 62 is not commensurate with the disclosure of the as filed specification for the reasons of record.

35 U.S.C. 112, first paragraph, scope of enablement

Claims 54 and dependent claims 55-60 remain rejected and new claim 62 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 54-60 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for:

An implantable medical device, comprising;

A multi-strip bioabsorbable collagenous based submucosa, wherein a radiopaque marker is disposed in between collagenous layer segments of said multi-strip bioabsorbable collagenous based submucosa to promote remodeling of tissue of the patient at a site at which said bioabsorbable collagenous based submucosa is implanted, does not reasonably provide enablement for a radiopaque, implantable biomaterial device, comprising:

a multi-layer bioabsorbable collagenous biomaterial including multiple collagenous layer segments that are bonded to one another, wherein said multi-layer bioabsorbable collagenous biomaterial comprises a material isolated from a warm-blooded vertebrate tissue source and is effective to promote remodeling of tissue of the patient at a site at which said collagenous biomaterial is implanted, and a radiopaque marker disposed in between collagenous layer segments of said multi-layer bioabsorbable collagenous biomaterial.

As discussed above, and for the reasons of record, the disclosure provided by the applicant is not fully enabled for the scope embraced by the claims because applicant does not provide sufficient guidance to demonstrate that he is in possession of any variety of suitable bonding techniques and materials as embraced by the invention and set forth and claimed. The disclosure provided by Applicant must encompass a wide area of knowledge to enable one of ordinary skill in the art at the time the invention was made to practice the invention without undue experimentation.

***Claim Rejections - 35 USC § 103***

Claims 36-45 and 53 remain rejected under 35 USC § 103 as being unpatentable over Voytik-Harbin et al., et al., et al., (US Patent No. 6,444,229) in view of Stinson et al., (US 2004/0111149 A1).

On page 10 of Remarks, Applicant argues that the '149 application to Stinson does not suggest the desirability of an injectable radiopaque composition. Moreover, Applicant states that the '149 application does not contains the term injectable or "implantable endoprosthesis". Further, Applicant argues that the '149 application specifically teaches away from forming such compositions. The comments are not persuasive.

Though the '149 application to Stinson does not suggest the desirability of an injectable radiopaque composition, Voytik-Harbin, as indicated in the previous office action, teaches the desirability of an injectable biomaterial gel. Stinson complements the teachings of Voytik-Harbin by teaching the need for bioabsorbable radiopaque markers for use on an implantable biomaterial as an endoprosthesis in order to improve radiopacity and the localability of the endoprosthesis during the various medical procedures. In determining the difference between the prior art and

Art Unit: 1633

the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious but whether the claimed invention as a whole would have been obvious. As indicated in the previous office action, it would have been obvious of one of ordinary skill in the art to mix a radiopaque powder material with the an injectable biomaterial gel because Stinson teaches that there is a need for bioabsorbable radiopaque markers for use on implantable biomaterials such as an endoprosthesis to improve radiopacity. Hence, the prior art references combined teach all the claimed limitations.

On page 10 of Remarks, Applicant argues that the '149 application to Stinson often describes the radiopaque marker as being "disposed on adjacent the endoprosthesis" and Applicant defines what threaded and discrete bioabsorbable-radiopaque markers are to conclude that the "implantable devices described here are simple not injectable compositions" (page 11 of Remarks). Such is not persuasive.

The '149 application to Stinson teaches that the marker is adapted to be disposed on or adjacent the endoprosthesis [0031]. Moreover, Stinson discloses a number of patterns for the deposition or mixing of the radiopaque substance with the implant material [0023], including localization of the bioabsorbable-radiopaque marker on portions of the outside surface of the implantable endoprosthesis (see Fig. 3a, [0056]). As such, with regards to the limitation of independent and currently amended claim 45 reciting the limitation of "a spreadable radiopaque marker spread along the surface of the bioabsorbable collagenous material", the radiopaque marker is disposed along the outside surface as taught by Stinson anticipates the claimed invention.

Art Unit: 1633

Claims 45-53 remain rejected under 35 USC § 103 as being unpatentable over any of Kropp (Urology, 1995), Whitson (US patent No. 5,997,575) and Bonadio (US patent No. 5,942,496) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

Claims 45-53 remain rejected under 35 USC § 103 as being unpatentable over any of Badylak et al., (WO 96/24661), Badylak 2 (WO 96/25179), Cook et al., (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

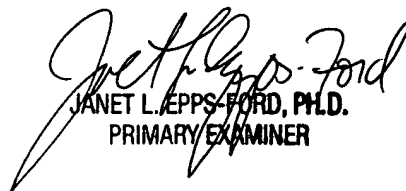
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nguyen Dave can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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